REMARKS

The following remarks are submitted to be fully responsive to the final Official Action dated December 5, 2008. This response is thus timely submitted within the three-month shortened statutory period for response. Should any fees be required, the Commissioner is authorized to charge Kagan Binder Deposit Account No. 50-1775 and thereafter notify us of the same. Reconsideration of all outstanding grounds of the rejection and allowance of the subject application are believed in order and respectfully requested.

The subject application was under appeal, with an Appeal Brief being filed by the Applicant on September 10, 2008. Prosecution was subsequently reopened, and a new ground of rejection was set forth in the final Official Action, mailed December 5, 2008, to which these Remarks are responsive. It was noted by the Examiner in the final Official Action, that the Applicant's arguments set forth in the Appeal Brief were fully considered but were not found to be persuasive. The Examiner also provided that the new ground of rejection combines prior art elements rather than substitutes them, as in the rejection dated February 5, 2008.

Prior to addressing the new prior art rejection of record, Applicant requests withdrawal of the finality of the subject Office Action to which this paper is responsive. The new ground of rejection of record presented in the Office Action is based upon the same primary reference (the Duhaylongsod et al. reference) as was relied upon by the Examiner in the previous rejections of record and as were appealed, but with a different theory of alleged obviousness. In this regard, the Examiner states within the final Official Action, dated December 5, 2008, that Applicant's arguments as presented in the Appeal Brief are unpersuasive. Yet, the Examiner has reopened prosecution of the subject application with a new ground of rejection. Applicant submits that, in fact, Applicant's arguments are and were persuasive. As a result, the Examiner was convinced that the prior rejections of record were insufficient, and has changed the rejections of record on at least a fundamental aspect.

The Examiner's attention is also directed to the conditions of reopening prosecution and for making a new ground of rejection of record as set out in MPEP, section 1207.04, entitled "Reopening of Prosecution After Appeal." Within this section, it is stated that:

> The examiner may, with approval from the supervisory patent examiner, reopen prosecution to enter a new ground of rejection after appellant's brief or reply brief has been filed. The Office action containing a new ground of rejection may be made final if the new ground of rejection was (A) necessitated by amendment, or (B) based on information presented in an information disclosure statement under 37 CFR 1.97(c) where no statement under 37 CFR 1.97(e) was filed. See MPEP § 706.07(a). >Any after final amendment or affidavit or other evidence that was not entered before must be entered and considered on the merits.

Within the subject Official Action, the Examiner states that the action is made final as necessitated by the amendment filed by Applicant on July 2, 2007. However, subsequent to that amendment, which was the last time the claims were amended, the Examiner has issued two other final Official Actions dated October 9, 2007, and February 5, 2008, with an after-final response being made by Applicant between them on January 9, 2008 and subsequent to both Official Actions, on May 5, 2008. A further advisory action was issued on June 6, 2008. No amendment has been submitted by Applicant after the most recent final action or even the previous one. It is submitted that the Examiner has had ample opportunity to introduce this new ground of rejection, and that the finality of the subject Official Action was in no way necessitated by any amendment. Moreover, the new ground of rejection is not based upon any information in an Information Disclosure Statement.

Accordingly, Applicant submits that the subject Official Action has prematurely been deemed as a Final Rejection, and Applicant respectfully requests withdrawal of such finality.

Claims 1-20 and 32-42 are pending in the application. Claim 15 has been withdrawn, and claims 21-31 have been canceled. Claims 1-14, 16-20, and 32-42 have been rejected, as described below.

Claims 1-3, 5-7, 9-13, 32-34, 36-38, 40 and 41 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. (U.S. Patent No. 6,241,741 B1).

In rejecting claims 1-3, 5-7, 9-13, 32-34, 36-38, 40 and 41 under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al., the Examiner attempts to combine aspects of two separate and distinct embodiments (one from Figures 5-8 and the second from Figures 18-20) from the reference, which, according to the Examiner's express statements, is different from the prior alleged combination of the distinct embodiments requiring a substitution of elements from one embodiment to the other embodiment. However, the Applicant asserts that it still does not make sense to combine aspects of the two separate embodiments of Duhaylongsod et al. in such a way as presented by the Examiner. It does not make sense to combine the two embodiments

because they: 1) use two, different physical approaches, which approaches have different design considerations; and 2) serve different functions based upon such design considerations.

First, the physical approach of catheter 80 in the embodiment of Figures 5-8 is from outside the vessel. In the embodiment, a fastener 10 with a graft vessel 12 attached is radially compressed for insertion within a slit in a side wall of a vessel 14 (col. 7, lines 17-21, 25-26). Balloon catheter 80 is inserted through the graft vessel 12 and the fastener 10 in order to expand the fastener 10 against the inner wall of the vessel 14 (col. 7, lines 21-25). Therefore, the physical approach of catheter 80 is from outside the vessel 14.

On the other hand, the physical approach of catheter 90 in the embodiment of Figures 18-20 is intravascular. Catheter 90 is advanced intravascularly through an artery 14 in order to extend out of an opening 18, and retract a fastener 50 back into the opening 18 (col. 8, lines 17-19, 28-36). Therefore, the physical approach of catheter 90 is intravascular.

Since the physical approaches of the catheters of the two embodiments of Duhaylongsod et al. are different, with one being extra vascular and the other being intravascular, each design requires different design considerations.

Design considerations are based upon the functionality that is required to complete these distinct physical approaches. The catheters of the two embodiments of Duhaylongsod et al. serve different functions. In the embodiment of Figures 5-8, catheter 80 is used to expand the fastener 10 to fit against the inner wall of the vessel 14. Blood flow in the vessel 14 is not intentionally occluded by catheter 80 or fastener 10 as a purposeful act that is required to perform the approach. Upon expansion of the fastener 10 by the balloon of the catheter 80, blood flow may be momentarily or partially occluded as a consequence of the expansion of the balloon within the fastener 10. However, the purpose of the expansion of the balloon of the catheter 80 is not to occlude blood flow through the vessel 14, but is to expand the fastener 10, and this expansion is performed as quickly as is practicable to secure the fastener 10 in place.

In the distinct embodiment shown in Figures 18-20, in order to deliver the fastener 50 to the artery 14, first, catheter 90 is advanced intravascularly into the artery 14 (col. 8, lines 28-32). Balloon 92 is inflated in order to occlude the artery 14 (col. 8, lines 18-22). Downstream from the balloon 92, a slit or opening 18 is made in the artery 14 (col. 8, lines 28-32) through which the fastener 50 is to be inserted into the vessel 14. Importantly, the purpose of balloon 92 on catheter 90 is to block blood from flowing though the artery 14 and out of the opening 18 during the procedure (col. 8, lines 20-22). That is, according to the method steps of this approach, blood is occluded for a period so that the incision or opening 18 can be made into the vessel 14 from

the side so that the catheter tip 90 can be advanced intravascularly out through opening 18, and threaded through fastener 50 (col. 8, lines 28-32). Fastener 50 and catheter 90 are then retracted back through opening 18 to deliver the fastener 50 to the vessel 14 (col. 8, lines 33-36). Once catheter 90 is retracted, blood is supplied downstream from the opening 18 though openings 98 on the end of catheter 90 (col. 8, lines 22-27). The catheter 90 includes two other balloons 94, 96 that are provided to expand the end portions 56 of fastener 50 to secure the fastener 50 in place in the artery 14 (col. 8, lines 19-22, 44-47).

One function or purpose of catheter 90 in the second embodiment, therefore, is to occlude blood flow to opening 18 during the anastomosis procedure. Because the procedure takes a significant amount of time, blood flow is occluded by balloon 92 for a significant amount of time (from before opening 18 is made in artery 14 and until after fastener 50 is delivered to artery 14). Because of the time that is required for blood flow to be occluded through artery 14, another function of catheter 90 is to supply blood to the artery 14 downstream from the anastomosis site through openings 98. Another function of catheter 90 is to expand fastener 50 to fit against artery 14 using balloons 94, 96 subsequent to occlusion, making the incision 18, loading the fastener 50, and positioning the fastener 50 within the artery 14.

The function of catheter 90 in the second embodiment of Duhaylongsod et al. is, therefore, significantly different than the function of catheter 80 in the first embodiment based upon the distinctions of the approaches. Catheter 80 of the first embodiment functions to expand fastener 10. On the other hand, catheter 90 occludes blood flow through artery 14 so that opening 18 may be made, delivers blood downstream from the opening 18, delivers fastener 50 to the artery 14, and then expands fastener 50 to fit in artery 14. Thus, it does not make sense to combine the catheter 90 of the second embodiment with the first embodiment. In fact, it is submitted that Duhaylongsod et al. recognized the distinction between the two embodiments and based upon their recognized distinctions of the approaches did not contemplate any provision of a blood supply element or step within the first embodiment of Figures 5-8. Since they certainly understood another approach where they disclose the use of a blood supply as a step of such approach, they, with that knowledge, disclosed the first approach with only a balloon catheter.

The Examiner attempted to combine the two embodiments by providing that the first embodiment disclosed the steps of: making an incision 18 in the blood vessel wall, inserting a tubular member 80 into a conduit 26, 12, advancing the tubular member through the incision located on a proximal end thereof, fixedly joining the conduit to the vessel wall, and after fixedly joining the conduit to the vessel, withdrawing the tubular member through the conduit. The

Examiner also provided that the embodiment shown in Figures 18-20 disclosed the step of providing oxygenated liquid flow through a tubular member and into the blood vessel while fixedly joining the conduit. The Examiner asserted that it would have been obvious to utilize the tubular member and conduit from the embodiment of Figures 18-20 in the embodiment of Figures 5-8 in order to provide blood through the tubular member and into the vessel during an anastomosis procedure.

However, Applicant asserts that it does not make sense to combine the embodiment of Figures 18-20 with the embodiment of Figures 5-8. In the embodiment of Figures 5-8, blood is flowing through the vessel. There is no intentional or lengthy occlusion of blood at the anastomosis site in the embodiment shown in Figures 5-8. The tubular member 80 is provided to expand the fastener 50. The tubular member 80 expands quickly to fit the fastener 10 against the inner wall of the vessel 14, and neither the tubular member 80 nor the fastener 10 occludes the vessel 14 for any significant amount of time, if at all. Therefore, a supply of oxygenated blood downstream from the location of the fastener 10 is not necessary in the embodiment of Figures 5-8. In the embodiment of Figures 18-20, on the other hand, the catheter 90 is advanced through the vessel intravascularly and the balloons 92, 94, 96 occlude artery 14. The purpose of balloon 92, in particular, is to occlude the flow of blood in artery 14 so that blood loss does not result through opening 18. In particular, balloon 92 remains inflated, occluding blood flow, for a significant amount of time. In that case, the delivery of blood downstream from the anastomosis site through openings 98 in the catheter 90 is desired to provide some blood flow downstream. In the embodiment of Figures 5-8, blood flow is already present as permitted through the vessel, and there is no disclosure of any reason why any additional supply would be useful or desired

Also, if the catheter 90 of the embodiment of Figures 18-20 were used in the embodiment in Figures 5-8 in place of catheter 80, the catheter would have to be inserted from outside the vessel at the anastomosis site itself. Thus, it would not be possible for balloons on the catheter to be located upstream from the anastomosis site for the purpose of occlusion of the vessel at the anastomosis site, while the openings would be downstream to supply blood downstream from the occlusion.

In sum, the two embodiments of Duhaylongsod et al. are completely different, and are provided using two different approaches and for two different functions. Thus, the two separate embodiments of Duhaylongsod et al. are not properly combinable to result in all elements of claim 1 being disclosed, taught or suggested in the reference in order to render claim 1 unpatentable under 35 U.S.C. 103. Accordingly, it is submitted that the Duhaylongsod et al.

reference does not render claim 1 obvious. Claim 1 is patentably distinct from Duhaylongsod et al. Thus, Applicant respectfully requests withdrawal of the rejection of record with respect to claim 1.

Independent claim 1 is patentably distinct from Duhaylongsod et al. for the reasons discussed above. Claims 2-3, 5-7, and 9-13 are dependent upon claim 1 and add further limitations to claim 1, and thus further add to the distinctness of the claimed invention. Thus, withdrawal of the rejection of record with respect to claims 2-3, 5-7 and 9-13 is therefore also respectfully requested.

Regarding independent claim 32, it is submitted that similar distinguishing aspects as in claim 1 are claimed over the Duhaylongsod et al. reference. Also, claim 32 recites a method of joining a blood conduit and a blood vessel, where a distal region of the conduit is fixedly joined to the blood vessel proximal end. The method described in claim 32 is an "end-to-end" anastomosis, which is different from an "end-to-side" anastomosis, which was the subject of claim 1, for example. Positioning the graft at or near the blood vessel proximal end, in claim 32, is done specifically for the purpose of performing an end-to-end anastomosis. An end-to-end anastomosis would not be possible if the graft was inserted at the position shown and described in Duhaylongsod et al., which is into a side wall of a vessel. Thus, the method of claim 32 is further distinct from the technique of the Duhaylongsod et al. reference, which does not disclose a graft connection to or near an end of any blood vessel. So, in addition to distinguishing on a similar basis as claim 1, claim 32 is further patentably distinct regarding the end-to-end anastomosis that is created according to the claim steps. Thus, withdrawal of the rejection of record with respect to claim 32 is believed proper and respectfully requested.

Independent claim 32 is patentably distinct from Duhaylongsod et al. for the reasons discussed above. Claims 33-34, 36-38, 40 and 41 are dependent upon claim 32 and add further limitations to claim 32, and thus further add to the distinctness of the claimed invention. Withdrawal of the rejection of record with respect to claims 33-34, 36-38, 40 and 41 is therefore also respectfully requested.

Claims 4 and 35 have again been rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. in view of Stanish (U.S. Patent No. 6,585,762 B1).

Claims 4 and 35 are dependent upon claims 1 and 32, respectively. Therefore, based upon the discussion above, claims 4 and 35 are similarly not rendered obvious by Duhaylongsod et al. Claims 4 and 35 are rejected as being unpatentable over Duhaylongsod et al. in view of

Stanish. However, Stanish does not remedy any deficiencies of Duhaylongsod et al. in order to render claims 4 and 35 unpatentable.

In the final Official Action, with regard to claims 4 and 35, the Examiner provided that Duhaylongsod et al. failed to disclose fixedly joining, including suturing, the conduit to the blood vessel, and further provided that such suturing was disclosed by Stanish. Stanish discloses suturing of a graft to a vein, but the reference is not properly combinable with Duhaylongsod et al.

In Duhaylongsod et al., suturing of the conduit 26, 12 is not necessary or desired. For example, in the embodiment of Figures 5-8, the graft vessel 12 or conduit is attached to a fastener 10 that is expanded using a balloon catheter 80 in order to seal the graft vessel 12 to the artery. There is no need for sutures in that embodiment. In the embodiment of Figures 18-20, for another example, the conduit is attached or sutured to a fastener 50 that is joined to the blood vessel when balloons on catheter 90 are inflated and expand the ends of the fastener 50 to press against the inside of the blood vessel wall. There is also no need for sutures in that embodiment. Duhaylongsod et al. actually teaches away from using sutures to join a conduit to a blood vessel, and teaches the use of expandable fasteners instead. The specification of Duhaylongsod et al. even provides that an aspect of the invention is to allow two vessels to be "sealingly secured to one another without the need for sutures" (col. 1, lines 52-54).

Accordingly, it is submitted that the Duhaylongsod et al. in view of Stanish do not render claims 4 and 35 obvious. Withdrawal of the rejection of record with respect to claims 4 and 35 is therefore also respectfully requested.

Claims 8, 14, 16-20, 39, and 42 have again been rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. in view of Amor et al. (U.S. Patent No. 6,059,809).

Claims 8, 14, 16-20, 39 and 42 are dependent upon independent claims 1 and 32. Therefore, based upon the discussion above, these claims are similarly not rendered obvious by Duhaylongsod et al. Claims 8, 14, 16-20, 39 and 42 are rejected as being unpatentable over Duhaylongsod et al. in view of Amor et al. Amor et al., however, does not remedy any deficiencies of Duhaylongsod et al. in order to render claims 8, 14, 16-20, 39 and 42 unpatentable.

In the final Official Action, the Examiner provided that Duhaylongsod et al. failed to disclose "inserting a stiffening member within the tubular member and wherein the expanding includes forcing the oxygenated fluid under pressure through the tubular member to expand the weakened distal region and into the blood vessel."

Amor et al. discloses a device used to implant or deliver stents to arteries. The device includes a stent pusher portion 2 comprising a microcatheter 4 with a guidewire 6 extending through a lumen 5 in the microcatheter 4. The device also includes a stent loading cavity 7 able to retain a stent 7, which is self-expanding. The distal end 9 of the device includes an atraumatic tip 10 which is prolonged by a tip balloon part 11 comprising an inflatable occlusive balloon 12 and a fluid releasing section 13. When the device is inserted into a body, the tip balloon part 11 leads the device. The shape of the tip balloon part 11, when the balloon 12 is deflated, is able to be changed to fit through the vascular system by advancement of the guidewire 6 more or less into the tip balloon part 11. The balloon 12 can be inflated to hermetically close the vessel upstream with respect to the stenosis to be cured. The fluid-releasing section 13 on the proximal face of the balloon 12, or just there behind, provides a flushing action upstream from the stent 7 placement in order to clean the vasculature. The fluid used for flushing is described as a physically acceptable fluid. The flushing action begins when the balloon 12 pressure reaches a given value, thus activating a controlled leak via the fluid-releasing section 13.

Amor et al. is not properly combinable with Duhaylongsod et al. For example, in Duhaylongsod et al., an anastomosis procedure is described, not an angioplasty procedure, as in Amor et al. In the anastomosis procedure of Duhaylongsod et al., for the embodiment shown in Figures 5-8, a blood conduit 12 is fastened into the blood vessel 14 using a fastener in order to bypass the stenosis 74 or blockage. Therefore, if a fluid was provided through the conduit 12 it would not be able to flush the blockage area because that area is bypassed. Regarding the embodiment in Figures 18-20 of Duhaylongsod et al., the conduit 12 is attached to the fastener 50 that is placed in a blood vessel 14, which does not even contain a blockage. Thus, there is no need to flush with a fluid in the embodiments shown in Duhaylongsod et al. Therefore, the Amor et al. and Duhaylongsod et al. references are not properly combinable.

Even if the two references were properly combinable, Amor et al. does not remedy the deficiencies of Duhaylongsod et al. For example, Amor et al. does not even disclose using an oxygenated fluid. In addition, there is no flow restrictor or bulb addressed by the two references, as in claims 8, 16 and 39 of the present invention. In some claims of the present invention, the flow of oxygenated fluid is used to expand a weakened distal portion of the tubular member. There is no flow of oxygenated fluid being used to expand a tubular member or catheter in either Amor et al. or Duhaylongsod et al. The use of a fluid in Amor et al. to flush an area near an angioplasty site free of debris is irrelevant to the present invention, in which an oxygenated fluid is provided to deliver oxygen to tissue downstream from an occlusion as well as to expand a

tubular member. Therefore, Amor et al. in view of Duhaylongsod et al. do not render claims 8, 14, 16-20, 39 and 42 unpatentable. Accordingly, withdrawal of the rejection of record with respect to claims 8, 14, 16-20, 39 and 42 is respectfully requested.

Conclusion

Applicant requests withdrawal of the finality of the Official Action to which this response is made. Also, it is submitted that claims 1-20 and 32-42 are currently in condition for allowance, a notice of which is earnestly solicited. If the Examiner finds any issue remaining after consideration of this response, the Examiner is invited to contact the undersigned, at the Examiner's convenience, in order to expedite any remaining prosecution.

Respectfully Submitted,

By: _____

Kimberly S. Zilling, Reg. No. 46,346
Customer Number 33072
Phone: 651-275-9846
Facsimile: 651-351-2954

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